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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,867	03/23/2004	Kai Desinger	3077	2699
7590 11/17/2006			EXAMINER	
Beck & Tysver, P.L.L.C. Suite 100 2900 Thomas Avenue S. Minneapolis, MN 55416			PEFFLEY, MICHAEL F	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary

Application No.

10/806,867

Applicant(s)

DESINGER, KAI

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 14-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/18/05; 9/22/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

Election/Restrictions

Claims 14-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 26, 2006.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/868,303, filed July 30, 2001. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen

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months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference

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in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electrode

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arrangement having a front cylinder and strip electrodes, the strip electrodes forming helical lines (claim 4) and the strip electrode with an optical waveguide (claims 7 and 12) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to show and/or describe the particular invention embodied in these claims. It appears as though applicant is selecting from a host of disclosed features and randomly claiming combinations of the features without expressly disclosing how the different embodiments are related or even feasible. For example, Claim 1 appears to be directed to the embodiment of Figures 7-10 which shows the strip electrodes. There is no disclosure of a "front cylinder" at the distal end of a carrier. Rather, the front tip portion is a solid, conical member (Figures 7 and 8) or a continuous tube (Figures 9 and 10) with no delineation between a cylindrical member and an insulating carrier. There is also no clear disclosure that the strip electrodes from this embodiment may be provided in a helical pattern, as shown in Figures 28 and 29. Rather, the helical pattern appears to be an entirely different embodiment that fails to show at least two electrodes formed as "strips". Similarly, there is no disclosure of an optical fiber used with the embodiment having strip-shaped electrodes, and certainly no disclosure of the strip-shaped electrodes applied directly onto an outside sheath of an optical fiber.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 lacks antecedent basis for "the insulating outside sheath", and is also unclear with the last few words of the claim "an elastically". It appears as though the last words are part of a grammatical and/or typographical error as the language does not make sense.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Imran (5,520,684).

As shown in Figure 2, Imran disclose a device that includes a front cylinder (i.e. end cap 51) with an insulating carrier (12) adjoining the cylinder and exposing two strip shaped electrodes (46 – Figure 4) which electrodes are formed by a metal tube having an externally applied insulating coatings (76). The electrodes are disposed in diametrically opposed positions on the carrier cross section (Figure 4). It is noted that the Imran "front cylinder" is a cylinder in the same manner as applicant's front cylinder (i.e. a solid cap member) on the embodiment having strip electrodes.

Claims 1-3, 7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hess et al (4,660,571).

Hess et al disclose a device that includes a front cylinder (57) connected to an insulating carrier (23). Disposed on the carrier are a plurality of strip shaped electrodes (33) that are disposed at diametrically opposite locations on the catheter member. An optical fiber (54) is disposed through a hollow lumen of the carrier and the electrodes are deemed to be applied in strip configuration on an insulating outer sheath (23).

Claims 1-5, 10, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleischman et al (6,146,379).

Fleischman et al disclose a device that includes strip-shaped electrodes (202) on an insulating carrier member (200) having a front cylinder member (see Figure 40). Figures 40-50 show several embodiments for the strip-shaped electrodes, including diametrically opposing electrodes (Figure 45) and a metal tube embodiment having an exposed electrode (Figures 49-50). Fleischman also teaches the electrodes may be provided in a helical configuration (Figures 47 and 48). Figures 40-45 show the electrodes applied as thin conductive strips on the carrier, and the terms "rigid" and "flexible" in claims 11 and 13 are broad enough that the Fleischman et al device is deemed to meet either one. That is, the device is clearly flexible and may be shaped to create lesions of a desired pattern, but is also rigid enough to be inserted through tissue to reach the desired treatment location.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al ('379) in view of the teaching of Chen et al (6,358,249).

The Fleischman et al device has been addressed previously. Fleischman et al teach of electrodes made from various materials, including layers of titanium, but fail to disclose the insulating materials as set forth in these claims. The examiner maintains that the use of any well known material for making medical grade electrodes is generally well-known in the art and a matter of obvious design consideration. Further, it is noted that applicant's specification fails to provide any criticality or unexpected results associated with the selected materials.

Chen et al is cited as a general teaching that it is known to make electrodes from various metals as well as the use of aluminum-oxide layers as insulation (see col. 9, lines 60+) for electrodes in an electrosurgical device.

To have provided the Fleischman device with any well-known insulation material to insulate the electrode members would have been an obvious design consideration for one of ordinary skill in the art, particularly in view of the teaching of Chen et al who disclose the use of aluminum oxide as an insulating material.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al ("379) in view of the teaching of Laufer (6,036,687).

Fleischman et al disclose various embodiments for the catheter device, but fail to specifically disclose the conical or wedge shaped tip members as recited in claims 8 and 9.

The examiner again maintains that tip members are generally known to come in a variety of shapes to facilitate the specific use of the device. That is, catheters may have rounded tips to facilitate passage through the vasculature without rupturing the vasculature, or may have conical or wedge shaped tips to facilitate passing the device through tissue or through a blockage in the vasculature. Fleischman et al teach of providing a sheath having a penetrating tip to advance the catheter into select tissue sites, but fails to disclose a catheter having a specific conical or wedge shaped tip.

Laufer et al disclose an analogous catheter device, and specifically teach that the catheter may have a rounded tip (e.g. Figures 8-10) or may have a more pointed conical or wedge shaped tip (Figures 17 and 19) to facilitate it's placement into particular tissue locations.

The examiner maintains that it would have been an obvious design consideration for one of ordinary skill in the art to provide the Fleischman et al catheter with a wedge or conical-shaped tip member to facilitate its placement into a particular tissue location, particularly since Fleischman et al disclose the device is used in procedures that require the penetration of tissue and further in view of the teaching of Laufer et al who teach

that it is known to provide a catheter with a more sharpened distal tip to facilitate placement in tissue.

Conclusion

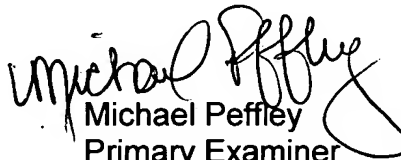
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Petruzzi et al (4,765,331) and Wang et al (5,462,545) disclose other catheter devices that includes strip-shaped electrodes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Michael Peffley
Primary Examiner
Art Unit 3739

mp
November 13, 2006